JUN 24 2011

510(K) SUMMARY: IMPAX VOLUME VIEWING

Common/Classification Name: Picture Archiving and Communications System 21CFR 892.2050
Proprietary Name: Impax Volume Viewing
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Koen Cobbaert, Prepared: May 6, 2011
Telephone: 32 3 444 7539

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's Impax Volume Viewing software, which is an accessory to its Impax picture archiving and communications systems. It is substantially equivalent to Agfa's Registration and Fusion software (K080013) in the majority of its functionality and to the Voxar 3D Enterprise with ColonMetrix and PET/CT Perfusion (K070831) with respect to its vessel viewing functionality.

B. DEVICE DESCRIPTION

The new device is similar to the predicate devices. All are PACS system accessories that allow the user to view and manipulate three dimensional image data sets.

Principles of operation and technological characteristics of the new and predicate devices are the same. The intended uses of the new and predicate devices are also the same.

C. INTENDED USE

Impax Volume Viewing software is a visualization package for PACS workstations. It is intended to support radiographer, medical imaging technician, radiologist and referring physician in the reading, analysis and diagnosis of DICOM compliant volumetric medical datasets. The software is intended as a general purpose digital medical image processing tool, with optional functionality to facilitate visualization and measurement of vessel features.

Other optional functionality is intended for the registration of anatomical (CT) on functional volumetric image data (MR) to facilitate the comparison of various lesions. Volume and distance measurements are intended for evaluation and quantification of tumor measurements, and other analysis and evaluation of both hard and soft tissues. The software also supports interactive segmentation of a region of interest (ROI).

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's Impax Volume Viewing has an Indications For Use Statement largely similar to the statements for the two predicate. Intended uses are the same. As software accessories to PACS systems, the predicate and new devices have the same technological characteristics. Software is used to identify characteristic patterns within 3D image data which the user can then view and manipulate. Descriptive characteristics and performance data are adequate to ensure equivalence.

Differences in the new device and the predicates do not alter their intended therapeutic/diagnostic effects.

PRODUCT COMPARISON TABLE			
	Impax Volume Viewing (NEW DEVICE)	Impax Registration and Fusion (PREDICATE K080013)	Voxar 3D Enterprise with ColonMetrix and PET/CT Perfusion (PREDICATE K070831)
3D Volume rendering	√	√	√
MPR, CPR	√	MPR	√
MIP, MinIP, AvgIP	√	MIP	√
Fusion and subtraction views	√	√	-
Can load and register two data sets for comparison	√	√	-
Multi-modality (CT and MR) image registration	√	√	-
Vessel analysis	√	-	√
Manual slice-by-slice volume-of-interest	√	√	-
DICOM and AVI movie generation	√	√	√
Reformat to a new dataset	√	√	√
Color maps	√	√	√
Annotations and measurements	√	√	√
Automatic table top removal	√	-	√
User interface	Impax	Impax	Voxar

E. TECHNOLOGICAL CHARACTERISTICS

Impax Volume Viewing is a software accessory to Agfa's Impax Picture Archiving and Communications system.

It is a tool for conveniently viewing and manipulating cross-sectional image series' for display in any orientation and slice thickness. A second series can be registered or fused to the first automatically, manually or with user defined landmarks. Segmentation of blood vessels and air-filled structures facilitate the visualization of vessel features. Color maps, subtraction views, multiple screen layouts and tools for measurement, calculations and annotations are provided.

F. TESTING

Verification and validation testing confirm the device meets performance, measurement and usability requirements. No clinical trials were performed in the development of the device.

The new device and Agfa's management systems conform to the following standards:

- EN12435:2006 - Health Informatics - Expression of Results of Measurements in Health Sciences
- ISO 14971:2007 - Application of Risk Management to Medical Devices
- ISO 13485:2003 - Medical Devices - Quality Management Systems - Requirements For Regulatory Purposes

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AGFA Healthcare N.V.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO NY 55313

AUG 23 2013

Re: K111638
Trade/Device Name: Impax Volume Viewing
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 10, 2011
Received: June 13, 2011

Dear Mr. Job:

This letter corrects our substantially equivalent letter of June 24, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Impax Volume Viewing

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Impax Volume Viewing is a visualization package for PACS workstations. It is intended to support radiographer, medical imaging technician, radiologist and referring physician in the reading, analysis and diagnosis of DICOM compliant volumetric medical datasets. The software is intended as a general purpose digital medical image processing tool, with optional functionality to facilitate visualization and measurement of vessel features.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111638